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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,639	07/20/2001	Daniel A. Vallera	09531-023001 / Z01015	2607
26211	7590	05/05/2006	EXAMINER	
FISH & RICHARDSON P.C.			JONES, DAMERON LEVEST	
P.O. BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	

1618

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/910,639

Applicant(s)

VALLERA ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-21, 23, 24, 26-29, 40-46, 48-50 and 52-65 is/are pending in the application.
- 4a) Of the above claim(s) 19, 42, 47, 52, 57, 60, and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 21, 23, 26-29, 40, 41, 43-45, 48, 49, 53-56, 58, 59, 61, 62, 64, and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the acceptable RCE filed 2/16/06. In addition, the Examiner acknowledges the amendment filed 2/16/06 wherein claims 1-17, 22, 25, 30-39, 47, and 51 are canceled; claims 18, 24, 41, and 48 are amended; and claims 52-65 are added.

**Note:** Claims 18-21, 23, 24, 26-29, 40-46, 48-50, and 52-65 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments/amendment filed 2/16/06 to the rejection of claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

### **112 Rejections**

The 112 rejections are WITHDRAWN because Applicant amended the claims to overcome the rejections.

### **103 Rejections**

The rejection of claims 18, 20, 21, 23, 26-29, 40, 41, 43-45, 48, 49, 53-56, 58, 59, 61, 62, 64, and 65 under 35 USC 103(a) as being unpatentable over Pastan et al (US Patent No. 5,990,296) in view of Goldenberg (US Patent No. 5,332,567) in further view of Jagtap et al (US 2002/0095044) and Kuo (US Patent No. 5,476,866) is MAINTAINED for reason of record in the office action mailed 3/10/05 and those set forth below.

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Applicant asserts that the claims have been amended to overcome the cited prior art. In addition, Applicant asserts that the references do not contain the necessary motivation to one of ordinary skill in the art to combine the teachings.

The rejection is being maintained on the basis that the cited prior art of references still read on the amended invention. For example, Pastan et al disclose B cell monoclonal antibodies that are useful in the killing or inhibiting the growth of cells in a subject. Thus, the amended claims are not distinguished over the cited prior art for reasons of record in the office action mailed 3/10/05.

In regards to the references not possessing the necessary motivation to be combined, the Examiner is aware that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. Thus, the reference were evaluated for what they suggested to one versed in the art.

**WITHDRAWN CLAIMS**

3. Claims 19, 42, 47, 52, 57, 60, and 63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

**COMMENTS/NOTES**

4. It is once again noted that Applicant's elected species is allowable over the prior art of record (elected species: toxic domain is diphtheria toxin; targeting molecule is


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Her-2/Neu; and the radionuclide species is  $^{64}\text{Cu}$ ). The search was expanded to the conditions wherein the toxic domain is diphtheria toxin; any radionuclide; an sFv of an monoclonal antibody for B cells. The search was not further expanded since prior art was found which could be used to reject the claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1618

May 1, 2006